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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,265	11/14/2003	Nadine Ferdman Burton	051438-5002	8062

9629 7590 06/29/2006

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EXAMINER
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HILL, LAURA C

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER

20060616

DATE MAILED:

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner for Patents**

# Office Action Summary

Application No.

10/712,265

Applicant(s)

BURTON ET AL.

Examiner

Laura C. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1 and 15 by Imonti (US 5,098,416) and all dependent claims therefrom (see Remarks pages 10-13 submitted 24 April 2006) have been considered but are moot in view of the new ground(s) of rejection as discussed below. It is noted that the new grounds of rejection are not based on the claim amendments but rather on the arguments presented by Applicant on 24 April 2006.

### ***Claim Language Interpretation***

2. It is noted that the interpretation of the term "actuator" (see page 2 of the Office action dated 24 January 2006) is not limited to a button as described on page 2 of the specification (see Remarks page 9). It is reiterated that the term "actuator" includes any type of mechanism that collapse/closes the fluid passage of the fluid conduit.

3. Claim 1 reciting "means for removably attaching the first housing portion to the second housing portion" has been interpreted to invoke 112, 6<sup>th</sup> paragraph means..for language. The 'means for...' is interpreted to be 'releasable connector such as hinge straps 222, 224 and latch 226' as recited in page 5, lines 1-10 of the specification.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-3, 5-7, 10-11, 13-24 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norelli (US 4,909,792; herein 'Norelli') in view of Shu (US

5,591,134; herein 'Shu'), and further in view of Powell (US 5,749,859; herein 'Powell'), and further in view of). Regarding claims 1-3, 15-16, 20-23 and 28 Norelli discloses medical device/syringe that creates a vacuum within the syringe by withdrawing the plunger from the syringe body (column 4, lines 5-11) with removable fluid conduit 10 having a first end for attaching to an aspiration cylinder/plunger end (figure 6) and a second end for attaching to a needle/cannula 12 (figure 3); a safety device/valve housing 50 for any type of medical purpose (column 5, lines 43-58) having semi-cylindrical jaws/first and second housing portions 52,54 that define a cavity for removably holding at least a portion of conduit 10 (column 4, lines 56-65 and figures 3 and 5); each jaw/housing portion is connected to the barrel 56 by a hinge 58 and 60, respectively to form a single-piece unit (column 4, lines 60-65). Norelli *does not expressly disclose* a hinge and latch means for removably attaching the first housing portion to the second housing portion. **Shu** discloses a protective needle cover 1 to be used with a needle and syringe (column 4, lines 24-27) made of plastic (column 3, lines 22-24 and column 4, lines 18-23) comprising first and second halves/housing 12,13 that are axially and pivotally connected together at one side by means of a connection portion 14 such that any one of the two halves is turnable about the connection portion 14 to be opened relative to the other half with a hinge mechanism (column 3, lines 24-32), said connection portion is in the form of a releasable latch comprising retaining hole/tab recess 15 and projected hook/latch tab 16 that firmly engage each other with a dome portion 122 to define a user interface space (column 3, lines 33-44 and lines 51-55, figures 3-4), said latch tab 16 and tab recess 15 formed on a respective one of the

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housing portions 12, 13 (figure 3) and thus providing an enclosing cover with side walls openable by compressing the side walls (column 2, lines 20-46). One would be motivated to modify the valve housing of Norelli with the hinge and latch means of Shu for a pivotable valve housing with openable walls since the references are in the same field of endeavor; medical cylinders with removable and enclosing valve housing. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the valve housing and thus providing a hinge and latch attaching means.

Norelli/Shu *do not expressly disclose* an actuator/conduit clamp for opening and closing the suction path defined by the fluid conduit. **Powell** discloses trocar 1 inserted into a cannula 5, 70 with a cannula tube 10 made of flexible plastic material (column 4, lines 8-20, column 3, lines 3-6 and figure 1), valve housing 13, 73 with openable and hinged wings 76, 77 (column 5, lines 22-28 and figure 10) enclosing fluid conduit 18, 75 (column 5, lines 22-24 and figures 3 and 10), and a button/actuator 20 coupled to the valve housing to close off the flow path through the cannula (column 3, lines 3-6 and column 4, lines 29-31). One would be motivated to modify the device of Norelli/Shu with the actuator for controlling the fluid path in the conduit since the references are in the same field of endeavor; medical cylinders with removable and enclosing valve housing mechanisms. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the device and thus providing an actuator.

Regarding claims 5-6 Norelli further discloses a first receptacle 80 proximate the first end of fluid conduit 10 for receiving an end of the aspiration cylinder to provide a

sealed connection (column 5, lines 54-56 and figure 6), wherein the fluid conduit 10 and first receptacle 80 comprise an integrally formed conduit component such that the path extends continuously through the conduit 10 (figure 6).

Regarding claims 7-8 and 27 Norelli further discloses conduit may be made from a flexible or elastomeric or plastics material such as silicone rubber (column 2, lines 31-34).

Regarding claims 10-11 and 24 Powell further discloses cap 6 that connects to first and second housing portions and extends outwardly from a housing end and over a portion of the fluid conduit (column 4, lines 14-15 and figure 1).

Regarding claims 13-14 Norelli further discloses gasket/sealing receptacle 134 that forms a fluid-tight seal between the valve housing portions of the fluid conduit and is integrally formed of the conduit (column 6, lines 50-61 and figure 10).

Regarding claims 17-19 Shu further discloses a double living hinge in which the first housing pivots relative to the second housing (figures 7 and 9).

5. Claims 4 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norelli (US 4,909,792; herein 'Norelli') in view of Shu (US 5,591,134; herein 'Shu'), in view of Powell (US 5,749,859; herein 'Powell') as applied to claim 1, and further in view of Mathias et al. (US 6,632,201; herein 'Mathias'). Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a

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showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Norelli/Shu/Powell disclose the housing is a plastic as per the discussion in claim 1 but *do not expressly disclose* the plastic is sterilizable polypropylene. **Matthias** discloses tubing set for use with needle and having needle protector 40 having first and second valve housing portions that open via hinge 66 (column 3, lines 53-63, column 4, lines 30-43 and figure 7). Matthias further discloses housing 42 may be made of any thermoplastic material for use in the medical field that can be sterilized such as polypropylene (column 4, lines 8-21). One would be motivated to modify the plastic housing of Norelli/Shu/Powell with the sterilized polypropylene plastic housing of Matthias since the references are in the same field of endeavor; medical devices with plastic opening protective coverings. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the plastic, thus providing a sterilizable polypropylene plastic.



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6. Claims 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norelli (US 4,909,792; herein 'Norelli'), in view of Shu (US 5,591,134; herein 'Shu'), in view of Powell (US 5,749,859; herein 'Powell') as applied to claim 1, and further in view of Lasaitis et al. (US 5,102,394; herein 'Lasaitis'). Norelli/Shu/Powell *do not expressly disclose* restrained movement of the fluid conduit relative to the valve housing. Lasaitis discloses catheter assembly 10 with needle 20 and conduit 16, shield member/valve housing 34 having projection/cap 30 which facilitates manipulation of the housing with respect to the conduit (column 3, lines 14-21 and lines 52-column 6, line 29) and thus inherently restrains movement of the two components with respect to one another. One would be motivated to modify the valve housing of Norelli/Shu/Powell with the movement control mechanism of Lasaitis for improved device stability since the references are in the same field of endeavor; fluid conduits enclosed by protective housing portions. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the valve housing, thus providing housings that engage the fluid conduit to restrain movement of the fluid relative to the housing.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Clement (US 6,193,672) is cited for showing a lavage 10 for suction and removal of body tissues having conduit 14 and valve housing with non-separable first and second walls 20,22 and thumb-engaging actuator 63 for controlling irrigation fluid or the vacuum. DeMichele et al. (US 6,156,015) is cited for showing a

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safety catheter made of polypropylene with valve housing having first and second mating walls 40,42, cap 26 and interior vacuum space 54 with cannula 18.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura C. Hill  
Examiner  
Art Unit 3761

LCH



TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

